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September 8, 2023

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, New Jersey 08101

Honorable Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower, Suite 1800
Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation*, Case No. 1:19-md-02875-RBK (D.N.J.)**

Dear Judge Kugler and Judge Vanaskie:

Please accept this letter on behalf of Plaintiffs in advance of the September 12, 2023 case management conference.

A. Manufacturer Defendants' Losartan/Irbesartan Discovery Disputes.

I. ZHP

a. Relevant Time Period: The Parties have reached agreement on the Relevant Time Period for custodial searches. For the following nine custodians, ZHP will search custodial files from January 1, 2008 to present:

- Baohua Chen
- Jun Du
- Peng Dong
- Jucai Ge

- Peng Wang
- Linhong Lin
- Remonda Gergis
- Hai Wang
- Eric Tsai

For the remaining custodians, ZHP will search custodial files from January 1, 2010 to present.

b. Search Terms: The Parties have reached agreement on search terms and will utilize in large-part the terms agreed to during the valsartan discovery phase of the case with minor additions and deletions. The primary losartan and irbesartan search terms are contained at Exhibit 1 and modifier terms are contained at Exhibit 2.

c. Custodians: The Parties are also pleased to report they have reached agreement on the list of custodians. A copy of said list is attached as Exhibit 3.

II. Hetero

a. Relevant Time Period

The parties have agreed that custodial discovery will begin January 1, 2014. The parties have been unable to come to an agreement on the end date for custodial discovery. Plaintiffs believe that the end date for custodial discovery should be through the present. Plaintiffs do not believe that extending that time period through to the present will present substantial additional burden, and that there likely continued to be activities, such as inspections of Hetero's facilities, etc., which retrospectively investigated and provided information regarding the contamination of Losartan with nitrosamines. Hetero believes that the end date for custodial discovery should be through December 31, 2019, with the exception for relevant communications to or from the FDA, which Hetero is willing to provide through the present.

For non-custodial discovery, the parties have agreed that the start and end dates shall be based upon the relevant time period needed to encapsulate the specific categories of documents. For example, for non-custodial documents related to the research and development of Hetero's Losartan Process II, documents will be produced related to the development of that process even if such documents are dated prior to January 1, 2014. Similarly, with regard to testing of Losartan produced using Process II for the presence of nitrosamines, testing results will be produced even if they occurred subsequent to December 31, 2019, if any exist.

b. Search Terms

For custodial productions, the parties have agreed to use the same search terms previously used for Valsartan discovery with the following modifications:

i. The ANDA/DMF numbers will be replaced with the relevant Losartan related ANDA/DMF numbers;
ii. The NDC codes will be replaced with the relevant Losartan NDC codes;
iii. The brand name drugs will be replaced with the relevant Losartan brand name drugs.

c. Custodians

In general, the parties believe that the custodians previously identified for Valsartan discovery are also applicable for Losartan discovery. The parties are continuing to work to finalize custodians, but have agreed to the following custodians subject to the confirmation of a few roles:

i. Surya GopalaKrishna Tummuri
ii. Panchakshari Nandyappa Gowda
iii. Venkata Praveen Kumar Penubaka
iv. Bhaskar Reddy Pabbatireddy
v. Ramesh Ramavath
vi. Ravinder Reddy Patlolla
vii. Tulasi Rao Pinjala
viii. Venkataramana Madireddy
ix. Vijaya Bhaskara Reddy Muvva

Hetero Labs Limited is continuing to work to identify additional custodians in their Research and Development and Business Development units who were involved with Hetero's development of their Losartan Process II, and who will be added to the agreed custodians listed above.

The parties are also working to confirm custodians for Hetero's US based affiliated entities (Hetero USA and Camber) but believe, as of the present time, that those custodians will also be the same as the ones previously identified for the Valsartan discovery.

III. Teva

a. Relevant Time Period

Finally, Plaintiffs and Teva have reached agreement in principle on the relevant time period for Teva's production. The start shall be May 1, 2020 to June 10, 2020, with certain documents or custodians postdating this time period additionally may be produced pending further discussions between the parties. This end date is based in part on Teva's unique circumstances insofar as its recalls and sales are ended a year before the end date and, further, the facility at which Teva made losartan closed prior to the end date as well.

b. Search Terms

The parties have reached agreement in principle on search terms, including a procedure for modifying terms if any term yields disproportionately large hits on not responsive documents.

c. Custodians

Plaintiffs and Teva have reached agreement in principle on custodians, and further have agreed to address potential supplemental custodians if they are identified in Plaintiffs' review of Teva's initial losartan productions.

IV. Torrent

a. Relevant Time Period

The parties have agreed to the beginning of the relevant time period for the custodial production to be January 1, 2014. However, the parties have a dispute as to the end of the relevant time period for the custodial production.

Torrent argues that the end of the relevant time period should be December 31, 2019 based on the date preliminarily identified by Plaintiffs in their Requests for Production of Documents before Plaintiffs had the benefit of discovery. That date was selected before Plaintiffs knew each Defendant's contamination story. Now, after receiving core discovery, Plaintiffs are confident that the Relevant Time Period is January 1, 2014 through the present. This timeframe encompasses Torrent's internal investigation after the recall, Torrent's nitrosamine testing protocols, and subsequent regulatory actions and communications between the FDA and Torrent. Of all the defendants, Torrent was the last or one of the last manufacturers to issue some of its recalls of contaminated losartan and Torrent did not issue these recalls until September 20, 2019.

As we learned in Valsartan, Torrent continued to investigate the causes of the nitrosamine contamination for years after they initiated the recall. In addition, one month after Torrent initiated the losartan recalls in September 20, 2019, the FDA issued a warning letter on October 15, 2019 for Torrent's Taluka-Kadi, Indrad, Gujarat facility (a facility where Torrent manufactured losartan) due to failure to follow written procedures for production and process control and failure to adequately investigate batch discrepancies. In September 2022, the FDA re-inspected Torrent's Taluka-Kadi, Indrad facility (the same facility where Torrent manufactured losartan) and the FDA issued another form 483 violation letter for contamination of its facility and again for failing to

adequately investigate products that failed lab testing. Plaintiffs have a right to the highly relevant documents regarding the communications surrounding the FDA's and Torrent's investigations that would have occurred before and after the FDA in October 2019 and in September 2022 found these violations at the factory where Torrent manufactured losartan. In addition, Plaintiffs have a right to the documents regarding communications of Torrent's investigations after Torrent issued its recalls in September 2019. Under Torrent's proposed timeframe, Plaintiffs would not receive the vast majority of these highly relevant documents.

b. Search Terms

The Parties have reached an agreement on search terms and will utilize in large part the terms agreed to during the valsartan discovery phase of the case with minor additions and deletions. The search terms are attached in Exhibit 4.

c. Custodians

The Parties have also reached an agreement on the custodian list and this list is attached as Exhibit 5.

V. Vivimed

a. Relevant Time Period.

The parties have reached an agreement as to the relevant time period for Vivimed. The Relevant Time Period for Vivimed with begin on January 1, 2011 to present.

b. Search Terms:

Plaintiffs and Vivimed have had several meet and confers regarding search terms and have reached an agreement on the terms Exhibit 6.

c. Custodians.

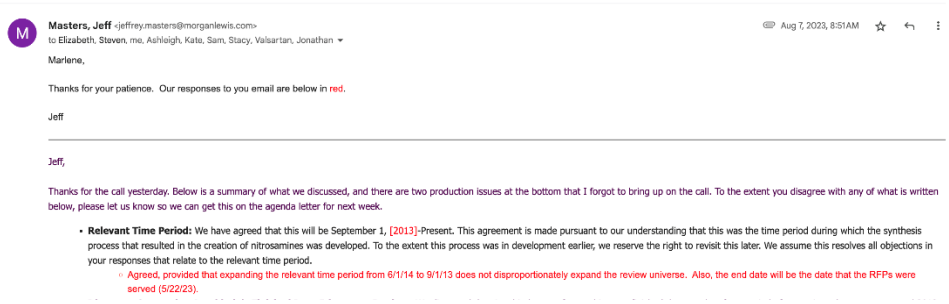
The parties are pleased to report that they have reached an agreement as to many custodians. The list of custodians is as follows:

1. Nagesh Majeti – Director of Quality Assurance (2012-2023).
2. Ravi Prakash Reddy –VP Technical Operations and Alathur Site Head (2015-present).
3. Swamy KN – Sr VP Analytical Quality Control (2006-present).
4. Chandran Tiruvattar – Vice President Regulatory Affairs (2018-present).
5. Harikrishnan N- Senior Manager Supply Chain (2018-present)
6. Balu P- Quality Control (2016-present)
7. Humesh Kale- Quality Assurance (2007-present)
8. A. Arivarasu- Senior Manager in Manufacturing Storage & Transportation (3/8/17-present)
9. M. Senthilkumar – Senior Manager in Quality Assurance (4/1/16-11/30/22)

VI. Aurobindo

a. Relevant Time Period:

The parties reached an agreement as to when the relevant time period for Aurobindo should begin (September 1, 2013), but there remains a dispute as to when this period should end. Plaintiffs and Aurobindo had previously reached an agreement that the Relevant Time Period should end on the date the Requests for Production were served (on May 22, 2013), as shown in the email excerpt from Aurobindo's attorney, Jeff Masters, below:



Masters, Jeff <jeffrey.masters@morganlewis.com> Aug 7, 2023, 8:51AM
to Elizabeth, Steven, me, Ashleigh, Kate, Sam, Stacy, Valsartan, Jonathan

Marlene,

Thanks for your patience. Our responses to you email are below in red.

Jeff

Jeff,

Thanks for the call yesterday. Below is a summary of what we discussed, and there are two production issues at the bottom that I forgot to bring up on the call. To the extent you disagree with any of what is written below, please let us know so we can get this on the agenda letter for next week.

- **Relevant Time Period:** We have agreed that this will be September 1, [2013]-Present. This agreement is made pursuant to our understanding that this was the time period during which the synthesis process that resulted in the creation of nitrosamines was developed. To the extent this process was in development earlier, we reserve the right to revisit this later. We assume this resolves all objections in your responses that relate to the relevant time period.
  - Agreed, provided that expanding the relevant time period from 6/1/14 to 9/1/13 does not disproportionately expand the review universe. Also, the end date will be the date that the RFPs were served (5/22/23).

During meet and confers the parties had agreed that this would end on May 22, 2023, the date on which Plaintiffs' Requests for Production were served. However, Aurobindo subsequently changed its position and now wants the Relevant Time Period to end on December 31, 2019.

While Aurobindo contends this date is appropriate because its sales terminated by the end of that year, that was not where relevant discussions concerning Aurobindo, its contaminated irbesartan, or the FDA's involvement ended. While Plaintiffs do not currently have the benefit of seeing Aurobindo's internal documents from the most recent years, Plaintiffs are aware that as recently as January 2022, Aurobindo continued to receive warning letters[1] from the FDA directed to Unit I, which manufactured irbesartan. These warning letters described Aurobindo's "failure to evaluate the potential effect that changes may have on [its] intermediates and API" as shown below:

[1] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aurobindo-pharmaceutical-limited-618091-01122022.

> **1. Failure to evaluate the potential effect that changes may have on the quality of your intermediates and API.**
>
> Your firm failed to fully evaluate whether increasing your acceptable **(b)(4)** limit by **(b)(4)** in an **(b)(4)** API starting material **(b)(4)** would impact the quality of **(b)(4)** API. Following the initial rejection of several lots of the **(b)(4)** starting material for failing to meet specified **(b)(4)** limits (e.g., **(b)(4)** ppm observed, **(b)(4)** ppm specification), you performed a lab scale study to justify an increase in the acceptable **(b)(4)** limit. You only evaluated **(b)(4)** potential impurities formed via **(b)(4)** where **(b)(4)** and did not consider the generation of the other substituted potential impurities before increasing the **(b)(4)** limit in your **(b)(4)** starting material from **(b)(4)** ppm to **(b)(4)** ppm
>
> Further, instead of fully evaluating the effect of increasing the **(b)(4)** limit in the **(b)(4)** starting material, you relied on an **(b)(4)** step as part of your lab scale study, which was not a part of the approved or implemented large scale manufacturing process for the **(b)(4)** API at the time, to purge potential impurities without demonstrating that any potential impurities would be removed by **(b)(4)**. Lastly, you relied on the existing related substances analytical method to detect the new impurities without determining their relative response factors to assess if this analytical method was appropriate for the new impurities.

The FDA's letter to Aurobindo further notes that these issues have been ongoing since 2019 and persist at least through the date of this letter:

> **Repeat Deviations at Facility**
>
> In a previous Regulatory Meeting held July 29, 2019, FDA cited similar CGMP deviations. You proposed specific remediation for these deviations in your response. Repeated failures demonstrate that executive management oversight and control over the manufacture of drugs is inadequate.

Based on this, it is clear that additional evidence of Aurobindo's cGMP violations continued to be generated after Aurobindo's proposed end date for the relevant time period. In receiving a letter like this, teams of employees (including and especially those selected as custodians) would have needed to investigate these ongoing violations, draft responses, conduct meetings about the letters, and enact changes based upon the violations. Truncating the relevant time period earlier would prevent Plaintiffs from obtaining documents that allow them to establish Aurobindo's pattern of cGMP noncompliance.

b. Search Terms:

Plaintiffs and Aurobindo have had several meet and confers regarding search terms and have reached an agreement on the terms in Exhibit 7. The Parties may have disagreements in the future about whether and how many terms are subject to renegotiation after Aurobindo has collected its full set of documents, but there are no disputes ripe for the Court on search terms at this time. Plaintiffs' position is that Aurobindo and Plaintiffs have been discussing both custodians and search terms for weeks, and the attached list of search terms should therefore be final, pending extraordinary findings of erroneous or too many hits on a term that was not foreseeable through sampling that could have been done now.

c. Custodians:

The parties are pleased to report that they have reached an agreement as to all custodians. The list of custodians is as follows:

1. A. Vannur Reddy
2. Kalakada Narasimha Reddy
3. Vijay Kumar Handa
4. Blessy Johns
5. C.V. Satyendranath
6. Dasarathi
7. Gattupalli Madhava Ramprasad
8. Govindarajan Narayanan
9. Hanumanthu Penchalaiah
10. Hemant Kumar Sharma
11. Jaipal Reddy
12. Kurresambi Reddy
13. Madhusudhana Reddy
14. R. Nagaraju
15. Rajaeev TL
16. Ram Mohan A Rao
17. Ram Pravesh Singh
18. Shahid Siddiqui
19. Srinivas K. Rama

20. Subramanyam Maddala
21. Sudhakar Reddy Mandepudi
22. Swaminathan Srinivas

VII. ScieGen

a. Relevant Time Period:

The Parties agree that the Relevant Time Period for ScieGen should begin April 1, 2015 and further agree that for two custodians (Siva Reddy PV and Pailla Raghuram), the Relevant Time Period extends further to cover due diligence activities involving Aurobindo.

Plaintiffs believed that the Parties had agreed the Relevant Time Period would extend through the present based on conversations in which the Parties reviewed the Court's November 25, 2019 Order together and concluded that the Relevant Time Period, in that Order, went through the "present," but on August 31, 2023 counsel for ScieGen indicated that ScieGen had subsequently reached a different conclusion as to the Relevant Time Period that should apply for ScieGen. ScieGen now argues that the Relevant Time Period is December 31, 2019 based on the date preliminarily identified by Plaintiffs in their Requests for Production of Documents before Plaintiffs had the benefit of discovery. That date was selected before Plaintiffs knew each Defendant's contamination story.

Now, after receiving core discovery and conferring with ScieGen—as well as discussing the Court's November 25, 2019 Order with them—Plaintiffs are confident that the Relevant Time Period is April 1, 2015 through the present. Not only is this date consistent with the Court's prior Order, but it encompasses the recall, ScieGen's internal investigation, ScieGen's testing protocols, and subsequent regulatory actions and product development decisions made at ScieGen. For example, Plaintiffs do not yet know when (or why) ScieGen decided not to bring Irbesartan back

to market and whether ongoing testing and product development played any role in such a decision or, whether this decision is based on the inability of ScieGen's API supplier Aurobindo to manufacture API not contaminated with nitrosamines. Plaintiffs believe they are entitled to discovery on these matters.

b. Search Terms:

Plaintiffs and ScieGen have had several meet and confers regarding search terms and have reached an agreement as to the attached list of search terms (Exhibit 8). To the extent the parties have subsequent disagreements, those agreements will be resolved between the Parties as contemplated by Section 2 of the Search Terms protocol after documents are collected, based on hit count reports. It is Plaintiffs' position that the search terms list should therefore be final, pending extraordinary findings regarding search terms hits that were not foreseeable.

c. Custodians:

The Parties have reached an agreement as to custodians and have identified the following custodians:

1. Siva Reddy PV, Chief Operating Officer
2. Krishna Mohan (a/k/a Chilakamarthy Krishnamohan)
3. Bala Murali, Director, QA
4. Dr. Pannaa Raghuram, SVP CQC/RA
5. Joseph Romano, CFO (current)
6. Renee Reynolds, CFO (previous)
7. Vishnu Marisetti, Head of Analytical R&D
8. Prakash Rajendran, Deputy Manager, RA

While the Parties principally agreed that the above custodians would be produced for the Relevant Time Period, ScieGen agreed that custodians Siva Reddy PV and Pailla Raghuram would also be produced for two topics *beyond* the Relevant Time Period, specifically, the selection of

Aurobindo as an API supplier and enforcement of the Quality Agreement(s) with Aurobindo in 2012; the ScieGen Irbesartan ANDA was submitted on September 26, 2012.

B. Status Report Regarding Preparation of Losartan/Irbesartan Fact Sheets.

In light of Judge Vanaskie's ruling at the September 7, 2023 hearing, the Parties will meet and confer on the losartan/irbesartan fact sheets and will notify the Court if there are any outstanding disputes. Plaintiffs will be prepared to discuss the status of that meet and confer during the conference.

C. PFS Deficiencies and Orders to Show Cause.

Plaintiffs will be prepared to address this issue during the conference.

Respectfully,

ADAM M. SLATER

Cc: All counsel of record (via ECF)